

REMARKS

This Amendment is in response to the Office Action dated June 4, 2003. A Request for a One-Month Extension of time as well as the appropriate fee accompanies this Amendment.

**OATH/DECLARATION**

In response to Paragraph 2 of the Office Action, a new Declaration compliant with 37 C.F.R. 1.67(a) has been filed herewith.

**ABSTRACT**

In response to the Examiner's objections to the pending Abstract, a replacement Abstract, with markings to show changes made, is submitted herewith. Because the replacement Abstract is believed to comply with the Examiner's suggestions, withdrawal of the subject objections is respectfully solicited.

**RELATED APPLICATIONS**

The first paragraph of the specification, under the heading *Related Applications*, has been amended to recite the updated status of the parent application (U.S. Patent Application No. 09/520,624). Withdrawal of the Examiner's objections related thereto is therefore requested.

**BRIEF DESCRIPTION OF THE DRAWINGS**

In response to the Examiner's objections, a "brief description" of all previously non-described figures has been inserted into the specification. As each description is derived from the original specification or drawings, no

new matter is believed to have been added. Withdrawal of the Examiner's objections is respectfully solicited.

**REJECTIONS UNDER 35 U.S.C. 112, SECOND PARAGRAPH**

The Examiner has rejected claims 1-6 as being indefinite for failing to particularly point out and distinctly claim the subject invention. In response thereto, extensive amendments have been made to the claims in accordance with the Examiner's helpful suggestions. Entry and acceptance of the above amendments as well as the withdrawal of the subject rejections is respectfully requested.

With regard to the recitation of "leucocyte components", Applicant wishes not to limit the meaning of this claim phrase by providing a specific definition thereof. It is pointed out, however, that the phrase should be broadly interpreted to encompass any component which can be obtained by the fractionating methods described in the claim and/or in the specification (e.g. potentially anything contained within the cell membrane or portions of the cell membrane itself). Because the meaning of this phrase can, at least, be ascertained by performing such fractionations, the phrase is not believed to be indefinite and the rejection thereof is respectfully requested to be withdrawn. \*

**REJECTIONS UNDER 35 U.S.C. 102(b) AND 103(a)**

Claims 1-6 stand rejected alternately under 35 U.S.C. 102(b) as anticipated by Hashimoto et al., Gottlieb, or Wissler et al., or under 35 U.S.C. 103(a) over Gottlieb or Wissler et al. in view of admissions contained in the

specification of the instant application. Reconsideration of the rejections is respectfully requested.

Claim 1 recites a method of physically fractionating whole leucocytes in order to obtain isolated leucocyte components. Although at least one of the prior art references teaches isolation of a single leucocyte component (e.g. Wissler teaches to isolate angiotropins from leucocytes and Hashimoto teaches to isolate nucleic acids from leucocytes), no single reference teaches or even suggests a method for isolating substantially all (or even a plurality) of the cellular components isolated from a leucocyte physical fractionation. \*

*not recited in claims*

Furthermore, no prior art reference cited by the Examiner provides the incentive for one to seek to isolate the plurality of leucocyte components which result from a physical fractionation. In this regard, no prior art reference teaches that it is therapeutically effective to treat infected blood cells with leucocyte components obtained from the physical fractionation of cultured leucocytes obtained from healthy human individuals. The Examiner has pointed out that the specification of the instant application admits the publication of the use of whole leucocytes to treat a single specified disease. However, the use of a plurality of individual, isolated components obtained from cultured leucocyte fractionation to determine and produce therapies for a variety of different diseases is nowhere taught in the cited prior art nor admitted in the specification. More simply, even though it is known that a whole cultured leucocyte is effective for treating a single disease, it is not immediately apparent from such knowledge that various individual

components obtained from a leucocyte are effective for treating a variety of diseases.

Still furthermore, storage, transport, and administration of whole cultured leucocytes can be difficult and whole cultured leucocytes are therefore expensive. In contrast, isolated leucocyte components are more easily stored and can be chemically synthesized (e.g. into a drug) for more simplified administration at a cheaper cost.

In view of the above, because there is no incentive contained in the prior art for isolating the plurality of leucocyte components which result from a physical fractionation, and because claim 1 recites fractionating whole leucocytes to obtain a plurality of isolated components (which result in improved, more cost effective disease therapies), claim 1 is believed to be both novel and non-obvious and allowance thereof is respectfully requested. Because claims 2-6 depend from claim 1, allowance of such claims is additionally solicited.

*not claimed*

#### NEW CLAIMS 7-13

Claims 7-13 are newly presented herewith. Entry and consideration thereof is respectfully solicited.

Independent claim 7 recites a method for identifying a therapeutically effective leucocyte component. In the claimed method, cultured leucocyte components obtained from healthy human cells are first isolated and then selectively combined with blood cells obtained from humans having known diseases. After combination thereof, the effects of the leucocyte components on erythrocyte cells are observed. In particular, the combination in which the least erythrocyte degeneration and longest erythrocyte life span is observed


is selected as therapeutically effective for the known disease.

Because no prior art reference teaches the combination of method steps as recited, claim 7 and all claims dependent thereon are believed to be patentable. More particularly, no prior art reference discloses determining the therapeutic effects of leucocyte components by observing the effects of the leucocyte components on erythrocyte activity. Accordingly, the allowance of claim 7 and claims dependent therefrom is respectfully solicited.

Although all issues are believed to have been resolved herein, if any issues are determined to remain, the Examiner is invited to contact the undersigned telephonically so that such issues can be resolved most expeditiously.

Respectfully Submitted,

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